4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA-2015-D-3581]

Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled "Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff." The draft guidance document provides human cells, tissues, and cellular and tissue-based product (HCT/P) manufacturers, health care providers, and FDA staff, with recommendations for applying the criterion of "homologous use" as it applies to HCT/Ps. The interpretation and application of the homologous use criterion and related definitions have been of considerable interest to industry stakeholders since they were first proposed during the Agency's rulemaking on HCT/Ps.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 29, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information

submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-D-3581 for "Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002, or to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring MD 20993-0002, or you may send an email request to the Office of Combination Products at combination@fda.gov. If you are submitting a written request, send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lori Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; or Angela Krueger, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1666, Silver Spring, MD 20993-0002, 301-796-6380; or

Leigh Hayes, Office of Combination Products, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5125, Silver Spring, MD 20993-0002, 301-796-8938.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff." The draft guidance document provides HCT/P manufacturers, health care providers, and FDA staff, with recommendations for applying the § 1271.10(a)(2) (21 CFR 1271.10(a)(2)) criterion of homologous use. This guidance will improve stakeholders' understanding of the definition of homologous use in § 1271.3(c), and how to apply the regulatory criterion in § 1271.10(a)(2) to their HCT/P.

HCT/Ps are defined in § 1271.3(d) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. FDA has implemented a risk-based approach to the regulation of HCT/Ps. Under the authority of section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264), FDA established regulations under part 1271 for all HCT/Ps to prevent the introduction, transmission, and spread of communicable diseases. HCT/Ps are regulated solely under section 361 of the PHS Act and 21 CFR part 1271, if they meet the criteria provided under § 1271.10(a).

If an HCT/P does not meet all of the criteria set out under § 1271.10(a), and does not meet one of the exceptions in § 1271.15, the HCT/P will be regulated as a drug, device, and/or biological product under the Federal Food, Drug, and Cosmetic Act, and/or section 351 of the PHS Act (42 U.S.C. 262).

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on "Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirement of the applicable statutes and regulations.

In a separate document published elsewhere in this issue of the Federal Register, FDA is announcing a public hearing entitled "Draft Guidances Relating to the Regulation of Human Cells, Tissues or Cellular or Tissue-Based Products; Public Hearing; Request for Comments" to be held on April 13, 2016, to provide stakeholders with the opportunity to discuss FDA's policy on regulation of HCT/Ps related to the four draft guidances on the following topics: Homologous use, same surgical procedure exception, minimal manipulation, and adipose tissue.

In separate documents published elsewhere in this issue of the Federal Register, FDA is also reopening the comment periods to FDA's public dockets on the previously issued draft guidance documents on the following topics related to HCT/Ps: Minimal manipulation (Docket No. FDA-2014-D-1696), adipose tissue (Docket No. FDA-2014-D-1856), and same surgical procedure exception (Docket No. FDA-2014-D-1584).

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 1271 have been approved under OMB control number 0910-0543.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm or http://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/default.htm or http://www.regulations.gov. Persons unable to download an electronic copy of the draft guidance entitled "Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff" may send an email request to CDRH-guidance@fda.hhs.gov to receive an electronic copy of the document.

Dated: October 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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